No. 08-1120

In the Supreme Court of the United States

AMERICAN HOME PRODUCTS CORPORATION, D/B/A WYETH, ET AL., PETITIONERS

v.

MARCELO A. FERRARI, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF GEORGIA

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

The National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" for any injury that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1). The question presented is whether that provision preempts state law claims against a vaccine manufacturer based on alleged defects in the design of a vaccine subject to the Act.

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BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, because of mootness concerns, the petition for a writ of certiorari should be held pending the disposition of *Bruesewitz* v. *Wyeth, Inc.*, petition for cert. pending, No. 09-152 (filed Aug. 4, 2009), or be denied. The Court should grant the petition for a writ of certiorari in *Bruesewitz*, which presents the same question.

STATEMENT

Respondents brought this action in Georgia state court against petitioners, the manufacturers of vaccines administered to respondents' son. The suit alleged that the vaccines caused respondents' son to suffer neurological injuries because they contained the preservative thimerosal. The trial court dismissed respondents' de-

sign defect claims as preempted by the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*). The Supreme Court of Georgia ultimately reinstated the claims.

1. "[T]wo overriding concerns" prompted the Act: "the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of [a tort-based] approach to compensating those who have been damaged by a vaccine," and "the instability and unpredictability of the childhood vaccine market" due to vaccine manufacturers' fear of tort liability. H.R. Rep. No. 908, 99th Cong., 2d Sess. 7 (1986) (*1986 Report*). Accordingly, the Act is designed to encourage "development and distribution of vaccines that will further enhance the public health" (particularly those recommended for routine administration to children), and to compensate individuals injured by such vaccines by means other than tort law. *Ibid.*

The Act does so by, *inter alia*, establishing a National Vaccine Advisory Committee, funding vaccine research, promoting dissemination of information on vaccines, and collecting data on adverse events related to vaccine administration. 42 U.S.C. 300aa-5, 300aa-6(b), 300aa-25, 300aa-26, 300aa-28. Compensation for injuries comes primarily from the National Vaccine Injury Compensation Program, which offers "no-fault" monetary awards to individuals who suffer injuries causally associated with particular childhood vaccines. See *Shalala* v. *Whitecotton*, 514 U.S. 268 (1995). The program is funded by Congressional appropriations and an excise tax on each vaccine dose. 42 U.S.C. 300aa-10 to 300aa-19; 26 U.S.C. 4131.

To receive compensation for a vaccine-related injury or death, the injured party (or his legal representative) must file a petition in the Court of Federal Claims (CFC), naming the Secretary of Health and Human Services (Secretary) as respondent. 42 U.S.C. 300aa-11(a), 300aa-12(a) and (b). The claimant need show by a preponderance of the evidence only that he received a vaccine listed on the "Vaccine Injury Table"[1] and suffered a corresponding listed injury, or that a listed vaccine in fact caused or significantly aggravated any injury. 42 U.S.C. 300aa-11(c), 300aa-13(a). The claimant does not need to establish any defect in the vaccine or fault on the part of the manufacturer.

A petition for compensation is initially heard by a special master appointed by the CFC, whose decision is reviewable by the CFC, and in turn by the Federal Circuit. 42 U.S.C. 300aa-12(e)-(f). Awards cover medical costs, lost earning capacity, and pain and suffering. 42 U.S.C. 300aa-15(a). To ensure representation, the Compensation Program awards reasonable attorneys' fees even if there is no award to the claimant, provided the petition was brought in good faith on a reasonable basis. 42 U.S.C. 300aa-15(e).

The Act forbids a claimant from resorting immediately to a civil action for damages against the vaccine's manufacturer. Rather, he must first file a petition under the no-fault scheme and seek a judgment from the CFC. 42 U.S.C. 300aa-11(a)(2)-(3). If the claimant

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[1] The Secretary maintains the Table at 42 C.F.R. 100.3. To be included on the Table, a category of vaccine must be "recommended for routine administration to children" by the Centers for Disease Control and Prevention, 42 U.S.C. 300aa-14(e)(2) and (2)(A), and Congress must fund awards by subjecting the category of vaccine to the excise tax, Act of Aug. 10, 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat. 646.

elects to reject that judgment (and any award), or withdraws his petition after the special master or CFC fails to render a judgment within specified time periods, then the Act permits him to bring a civil action against the manufacturer. 42 U.S.C. 300aa-11(a)(2)(A), 300aa-21(a)-(b).

Such actions are governed by state law, subject to the Act's specific limitations. 42 U.S.C. 300aa-22. Among these limitations is the provision at issue here:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. 300aa-22(b)(1).

2. Relative to the tens of millions of childhood vaccine doses administered annually, the number of petitions in the CFC is small—reflecting the extraordinary safety of the covered vaccines. Since the first few years of the Compensation Program (which saw several thousand claims for injuries that pre-dated the Act), there typically have been 100 to 200 ordinary claims filed annually. Approximately one third of such claims are ultimately compensated, with the average award exceeding $750,000. See Health Res. & Servs. Admin., Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program Post-1988 Statistics Report* (Dec. 2, 2009) <http://www.hrsa.gov/vaccinecompensation/statistics_report.htm> (*Statistics Report*).

Not counted among these ordinary claims are more than 5600 petitions asserting a causal link between

childhood vaccines containing thimerosal (as well as certain measles-mumps-rubella (MMR) vaccines) and neurological damage; approximately 5000 such petitions remain pending and have been consolidated before the CFC in the Omnibus Autism Proceeding (OAP). See *Statistics Report*. Six "test cases" were identified in the OAP to present two "general theor[ies] of causation." See *Cedillo* v. *Secretary of HHS*, No. 98-916V, 2009 WL 331968, at *9-10, *11 n.16 (Fed. Cl. Feb. 12, 2009), aff'd, 89 Fed. Cl. 158 (2009), appeal pending, No. 2010-5004 (Fed. Cir. filed Oct. 7, 2009). In the test cases presenting the first theory, special masters ruled that vaccines did not cause the claimants' injuries, and the CFC has affirmed those decisions. *Ibid.*; *Hazlehurst* v. *Secretary of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), aff'd, 88 Fed.Cl. 473 (2009), appeal pending, No. 2009-5128 (Fed. Cir. filed Sept. 21, 2009); *Snyder* v. *Secretary of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), aff'd, 88 Fed. Cl. 706 (2009). In the test cases presenting the second theory of causation, the masters have held evidentiary hearings and received post-hearing briefing, and decisions are expected early this year. The CFC must decide each case in the omnibus proceeding individually (see 42 U.S.C. 300aa-12(d)(3), 300aa-13(a)), but the resolution of the test cases is expected to lead to efficient resolution of most of the remaining cases.

3. Respondents filed this action in state court against several vaccine manufacturers, including two of the petitioners here. Pet. App. 33-35; Compl. 2-3. The complaint alleged that respondents' son had suffered neurological injuries from exposure to vaccines produced by petitioners and approved by the Food and Drug Administration (FDA) that contained the preser-

vative thimerosal. Pet. App. 36. Petitioners moved for summary judgment, contending that respondents' claims are preempted by Section 22(b)(1). See *id.* at 34-37. As relevant here, the trial court granted that motion to the extent respondents' claims were based on the alleged design defect of using thimerosal. *Id.* at 49.

The Supreme Court of Georgia reinstated respondents' claims. The Georgia court construed "unavoidable" in Section 22(b)(1) by looking to the *1986 Report*, which commented on the text that became Section 22(b)(1). Pet. App. 7. That report states that Section 22(b)(1) was modeled on Restatement (Second) of Torts § 402A cmt. k (1965) (Comment k), which protects the seller of "unavoidably unsafe" products. Pet. App. 11 (quoting *1986 Report* 26 (quoting Comment k)). The Georgia court read the reference to Comment k as showing Congress's intent not to bar all design defect claims against vaccine manufacturers, but instead to allow juries to undertake a case-by-case analysis of whether a safer vaccine design was available. *Id.* at 7-10.

Pointing to the phrase "'if the [vaccine-related] injury or death resulted from side effects that were unavoidable,'" the court observed that "[t]he conditional nature" of this language demonstrated that Congress contemplated "the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable." Pet. App. 10 (first brackets in original) (quoting 42 U.S.C. 300aa 22(b)(1)). The court also relied on language in a post-enactment 1987 congressional committee report on legislation that funded awards under the Compensation Program. *Id.* at 13-14. In the court's view, that report offered a "strikingly clear and emphatic" indication that Section 22(b)(1) was not a categorical bar to design defect claims. *Id.* at 14.

4. Six months after petitioners sought review in this Court, respondents voluntarily dismissed their claims in state court without prejudice. Resp. Supp. Br. App. 1a-2a.

DISCUSSION

The Supreme Court of Georgia erred in holding that the Vaccine Act allows juries to resolve, on a case-by-case basis, claims that a vaccine approved by the FDA could have been designed in a way that would not have injured the plaintiff. That misunderstands the text of Section 22(b)(1), conflicts with the Act's legislative history, and frustrates Congress's intent to stabilize the market for vaccines critical to children's health. Congress intended through Section 22(b)(1) to exempt vaccine manufacturers from design-defect liability, while still offering, through other provisions of the Act, compensation to the injured and inducements to devise even safer vaccines.

The Georgia court's decision squarely conflicts with *Bruesewitz* v. *Wyeth Inc.*, 561 F.3d 233, 242-243 (3d Cir. 2009), petition for cert. pending, No. 09-152 (filed Aug. 4, 2009). Moreover, the question presented is pressing. While it remains unsettled, manufacturers' uncertainty about their potential liability for design defects may harm the public health by deterring their development and production of vaccines. At the same time, thousands of claimants in the OAP do not know whether they may seek civil tort remedies. The issue therefore warrants this Court's review. Because of a mootness question in this case, however, the Court should grant the petition in *Bruesewitz*, which presents the same question.

I. THE GEORGIA SUPREME COURT MISINTERPRETED THE VACCINE ACT'S PREEMPTIVE REACH

Section 22(b)(1) expressly preempts state law. See, *e.g.*, Pet. App. 4; *Bruesewitz*, 561 F.3d at 242-243. The task therefore is to "identify the domain expressly preempted by that language." *Medtronic* v. *Lohr*, 518 U.S. 470, 484 (1996) (internal quotation marks and citation omitted). The preemptive reach of Section 22(b)(1) turns on what Congress intended to convey by invoking the term of art "unavoidable." The Georgia Supreme Court concluded that the term is "most consistent with" a case-by-case approach, under which a claim is not preempted if a plaintiff can show that an injury from side effects was "avoidable by a feasible alternative design." Pet. App. 10-11. By contrast, petitioners contend that "unavoidable" conveys Congress's blanket determinations that childhood vaccines, although offering immense social benefits, must be "deemed to be 'unavoidably unsafe' because they carry an inherent risk of injury"—and that such products, in accordance with common law principles, should not expose their manufacturers to liability for design defects. Pet. 30. Petitioners' reading of Section 22(b)(1) is correct.[2]

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[2] Because Section 22(b)(1) is an *express preemption provision*, *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1193 (2009), which concerned implied preemption, is of limited relevance. Moreover, the precise question in *Levine* was whether federal drug labeling law impliedly preempted the plaintiff's claim that a drug should have borne more stringent warnings than approved by FDA. The Act here speaks directly to vaccine labeling by providing that a vaccine that complies with all FDA requirements "shall be presumed to be accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(2).

1. Pointing to the phrase "if the injury or death resulted from side effects that were unavoidable" (42 U.S.C. 300aa-22(b)(1)), the Georgia court concluded that "[t]he conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable." Pet. App. 10. From that premise, the court reasoned that claims based on avoidable design defects are not preempted, because if Congress had intended to bar all design defect liability, it could have said so more clearly. *Id.* at 10-11.

That approach to the statutory language is incorrect. "[I]t is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear." *Bruesewitz*, 561 F.3d at 246. The more relevant question is what the best reading of the actual language is. Here, that language indicates which side effects Congress thought avoidable and which it did not. The modifying clause beginning "even though" explicates the universe of "avoidable" side effects—*i.e.*, those caused by manufacturing defects or improper labeling. Side effects alleged to inhere in the vaccine's FDA-approved design are excluded from that list of "avoidable" side effects, for which civil liability is appropriate. The result is that Section 22(b)(1) bars one theory of liability (design defect), while leaving in place two others (manufacturing and labeling defects), subject to other limitations in the Act.

2. The Act's legislative history supports this understanding. The *1986 Report* explains (at 25-26) that "unavoidable" was drawn from Comment k, which concerns "*[u]navoidably unsafe products.*" Restatement (Second) of Torts § 402A cmt. k at 353 (1965) (caption).

Comment k recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and offers a vaccine as a prototypical example. *Ibid.* Under Comment k, such a product is "not defective" as a matter of law, and the seller cannot be held liable for the consequences of its use as long as it was "properly prepared and marketed" and accompanied by "proper warning." *Id.* at 354. Section 22(b)(1) codifies that rule.

The *1986 Report* states that the Committee invoked Comment k "because it intends that the principle in Comment K regarding 'unavoidably unsafe' products * * * apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system." *1986 Report* 26. In other words, vaccines covered by the Compensation Program would be deemed "unavoidably unsafe products," and thus not subject to design-defect claims. The *1986 Report* further explains:

> Given the existence of the [no-fault] compensation system in this bill, * * * [v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

Ibid.

The Georgia Supreme Court read this language as merely a prediction that vaccine claimants alleging design defects would find the new compensation system "appealing," despite being "authorized to [resort to] the

tort system." Pet. App. 13. That misunderstands the Report in two ways. First, the Report does not say that claimants are "authorized" to pursue tort remedies; to the contrary, it states that such claimants "should * * * *not*" "pursue recompense in * * * the tort system." *1986 Report* 26 (emphasis added). Second, the Georgia court's reading ignores the essential point of the quoted passage, which is that the Act treats design defect claims differently from claims based on manufacturing and labeling defects. Only the latter two theories can be pursued in the tort system.

To support its interpretation of Section 22(b)(1), the Georgia court also relied on language in a 1987 committee report that post-dated passage of the Act. Pet. App. 14 (citing H.R. Rep. No. 391, 100th Cong., 1st Sess. 691 (1987) (*1987 Report*)). According to that report, the codification of Comment k "was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." *1987 Report* 691. The report further stated that "[t]his question is left to the courts to determine in accordance with applicable law." *Ibid.*

The *1987 Report* is not persuasive authority for interpreting the Act as passed in 1986. It was prepared after Section 22(b)(1) became law. As this Court explained in *District of Columbia* v. *Heller*, 128 S. Ct. 2783 (2008), statements by those who drafted or voted for a law are relevant to statutory interpretation "not because they reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." *Id.* at 2805. Conversely, statements made after enactment "could have had no effect on the congressional vote." *Ibid.* To be sure, Section 22(b)(1) did not become

effective until the Compensation Program was funded by the appropriations that were the subject of the *1987 Report*. See Br. in Opp. 20. But Members of Congress who voted for the Compensation Program and the associated preemption provision in 1986 did so with the understanding not of some later document, but rather of the *1986 Report* that vaccine design should "not be the subject of liability in the tort system." *1986 Report* 26.[3]

3. Preemption of all design defect claims flows from the Act's structure and purpose as well. Fear of "instability and unpredictability of the childhood vaccine market" due to the threat of large tort liability was an "overriding concern[]" that prompted the Act. *1986 Report* 7; see also *Schafer* v. *American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994) (Breyer, C.J.) ("[A]n important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market.").

The Act would do little to address this problem if it permitted any vaccine claimant disappointed with the CFC's judgment to seek all the customary product liability tort remedies in a civil action. Indeed, consistent with Comment k's statement of the law, no or few States

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[3] The *1987 Report* also states (at 691) that when the House Committee on Energy and Commerce considered the original act in 1986, it rejected an amendment providing that "a manufacturer's failure to develop a safer vaccine was not grounds for liability." See House Energy & Commerce Comm., Markup Hearing on H.R. 5546, at 46-54 (Sept. 18, 1986) (rejecting amendment). The proceedings within a single committee's markup session are likewise not an authoritative guide to what Congress understood and intended in passing a bill. Rather, "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill." *Eldred* v. *Ashcroft*, 537 U.S. 186, 210 n.16 (2003) (quoting *Garcia* v. *United States*, 469 U.S. 70, 76 (1984)).

in 1986 would have imposed tort liability on a vaccine manufacturer absent a showing by the plaintiff of a safer alternative design. Thus, on respondents' view of the Act, Congress intended to preempt liability only for conduct that state law probably would not have held tortious in the first place. That result does little to address the burden of litigation or the threat of large and unpredictable tort judgments against vaccine manufacturers. At most, awards under the Compensation Program might satisfy or dissuade some number of claimants, somewhat reducing the number of potential civil tort plaintiffs.

Other parts of the Act also indicate that Congress intended more comprehensive and farther-reaching reform of the vaccine tort system than respondents suggest. The Act achieves the principal goals of product liability design defect law—compensation for the injured and incentives for safer products, see *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1202 (2009)—by other means.

The Compensation Program provides relief through a system that is simpler and more generous than the tort system. See *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995); *1986 Report* 6 ("[F]or the relatively few who are injured by vaccines * * * the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered."). Significantly, the Vaccine Injury Table controls the scope of the Act for both compensation and preemption purposes, ensuring that compensation is potentially available whenever tort remedies are preempted.[1]

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[1] The Compensation Program requires proof that the injured party received a vaccine on the Table. See 42 U.S.C. 300aa-11(c)(1)(A), 300aa-13(a)(1)(A). As for preemption, Section 22(b)(1) preempts only claims for "vaccine-related injury or death," which is by definition limi-

Safer vaccines are promoted through a rigorous FDA approval process. New childhood vaccines in particular are put through some of the most exhaustive examinations and largest clinical trials of any FDA-approved product. For example, development of new vaccines for rotavirus gastroenteritis began in the early 1980s and, after clinical trials involving more than 130,000 participants, culminated in FDA approval in 2006 and 2007 of the vaccines. See Stanley A. Plotkin et al., *Vaccines* 719-720 (5th ed. 2008); Roger I. Glass & Umesh D. Parashar, *The Promise of New Rotavirus Vaccines*, 354 New Eng. J. Med. 75, 76 (2006). Each type of vaccine subject to the Act has been approved by the FDA as a biological product following such an extensive process, or is currently undergoing FDA-regulated clinical trials. See 42 U.S.C. 262(a).[5]

Vaccine safety and innovation are also encouraged through direct government funding of research. Government-wide statistics are not readily available, but the National Institutes of Health (NIH) alone reports funding about $1.5 billion of vaccine research per year. See NIH, Dep't of Health & Human Servs., *Estimates of Funding for Various Research, Condition, and Disease Categories* (rev. May 7, 2009) <http://report.nih.gov/rcdc/categories>. In addition, expert government agencies (such as the Centers for Disease Control and Prevention (CDC)) and nongovernmental organizations (such as the American Academy of Pediatrics) have sig-

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ted to injuries "associated with one or more of the vaccines set forth in the Vaccine Injury Table," 42 U.S.C. 300aa-33(5).

[5] Conceivably some vaccines administered abroad to federal employees and their dependents would be covered by the Act, see 42 U.S.C. 300aa-11(c)(1)(B)(i)(II), but not subject to FDA regulation.

nificant influence over the vaccines that are administered to children.

The Act itself ensures continuous monitoring of vaccine safety by requiring that both vaccine manufacturers and health care providers report side effects (and other contraindicating reactions) to the Secretary through the Vaccine Adverse Event Reporting System. 42 U.S.C. 300aa-25(b); see http://vaers.hhs.gov. Mandatory reporting by health care providers of adverse events makes the reporting system for vaccines even more comprehensive than parallel systems applicable to drugs and non-vaccine biological products. Compare 42 U.S.C. 300aa-25(b) (vaccines), with 21 C.F.R. 600.80 (biological products generally), 21 U.S.C. 355(k)(1) (drugs), and 21 C.F.R. 314.80 (drugs).

Routinely administered vaccines are products for which the design trade-offs between safety and efficacy affect not only individual recipients, but also the entire society, which benefits from vaccines potent enough to ensure that a disease is contained or (as with smallpox) eradicated. See *Schafer*, 20 F.3d at 4. The tort system—in which juries may pay little heed to this social cost/benefit calculus, see *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008)—is poorly equipped to encourage optimally safe and effective vaccines. That is why Congress recognized through the Act that expert regulators should control design decisions, with relief available under the Compensation Program.

II. THE SPLIT BETWEEN THE GEORGIA SUPREME COURT AND THE THIRD CIRCUIT MERITS THIS COURT'S ATTENTION

A. The Georgia Supreme Court's decision directly conflicts with the Third Circuit's decision in *Bruesewitz*,

which held that Section 22(b)(1) preempts all design defect claims. 561 F.3d at 235, 251, 255.

Bruesewitz concerns a child who experienced seizures after her third dose of a diphtheria-tetanus-pertussis (DTP) vaccine. She ultimately suffered residual seizure disorder and developmental delay. Her parents pursued a timely but unsuccessful petition for compensation in the CFC, *Bruesewitz* v. *Secretary of HHS*, No. 09-266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002), and rejected the CFC's judgment pursuant to 42 U.S.C. 300aa-21(a)(1). They then sued the manufacturer of the DTP vaccine in Pennsylvania state court, alleging (as relevant here) that toxins inherent in the vaccine's design caused their daughter's injuries. The manufacturer removed the case on the basis of diversity of citizenship, and the district court granted summary judgment for the manufacturer, holding that the Act preempted the plaintiffs' design-defect claims. See *Bruesewitz*, 561 F.3d at 236-238.

The Third Circuit affirmed. It began with the Act's text, which it read to preclude tort litigation over at least some design defect claims. *Bruesewitz*, 561 F.3d at 245. The court noted that Section 22(b)(1) "primarily relates to design defect claims," because the other types of products liability claims (*i.e.*, for manufacturing or labeling defects) are dealt with in the "subordinate clause introduced by 'even though.'" *Ibid.* The Third Circuit rejected the Georgia court's textual analysis "because it does not bar any design defect claims"—that is, "[i]f we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." *Id.* at 246. The Third Circuit went on to conclude, based on legislative history, that

the Act preempts all design defect claims irrespective of whether they sound in negligence or strict liability. *Id.* at 247-250.

Bruesewitz expressly rejects the reasoning of the Georgia Supreme Court. See *Brueswitz*, 561 F.3d at 248 ("In our view, the [1986] Report supports the conclusion that the Vaccine Act preempts all design defect claims."); *id.* at 246 ("[T]he *Ferrari* Court's construction [of Section 22(b)(1)] is contrary to the structure of the Act because it does not bar any design defect claims."); *id.* at 250 ("[W]e have no basis to conclude that the [1987] Report is an accurate reflection of * * * the motivations underlying Congress's enactment of the Vaccine Act in 1986."). The conflict is thus squarely presented.[6]

B. The question presented is already informed by thorough analyses from several trial and appellate courts, and further attention from lower courts would contribute little to the debate. The issue has nationwide significance, and a decision from this Court would foster sound judicial administration and advance the public health, for three reasons in particular.

1. The question presented is important to more than 5000 claimants in the OAP currently pending before the CFC. To date, those claimants have been unsuccessful.

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[6] Respondents would avoid the conflict by confining *Bruesewitz*'s holding to preemption of DTP design-defect claims, based on the Third Circuit's observation (561 F.3d at 250) that Congress was particularly concerned with DTP-related claims in passing the Act. See Br. in Opp. 21. But the distinction respondents perceive would dismiss nearly all of the Third Circuit's analysis as dicta, and that distinction has no basis in the law. The Act draws only one relevant distinction: between vaccines that are on the Table and those that are not. See, *e.g.*, 42 U.S.C. 300aa-11(c)(1)(A) and 300aa-33(5).

If that remains the case, many may elect to pursue tort remedies against manufacturers. Efficient judicial administration counsels early resolution of threshold legal issues likely to arise in those suits.

2. Fears of design defect liability could stall vaccine innovation while the law remains unsettled. Routine childhood vaccines typically have such a low rate of unavoidable serious side effects (sometimes numbering in the single digits per million doses) that they may not be discovered even in massive clinical trials. Public health would be undermined if manufacturers chose not to pursue research and development of new vaccines for fear of unknown exposure to liability. Current research offers several examples of vaccine development strategies that promise significant advantages in safety and efficacy, but that may result in unknown rare side effects:

- *Adjuvants.* Currently, many childhood vaccines must be administered in multiple doses to confer lasting immunity. Adding certain compounds (known as adjuvants) to the vaccine may so improve the immune response that fewer doses are needed. See, *e.g.*, P. Helena Mäkelä, *Vaccines, Coming of Age After 200 Years*, 24 FEMS Microbiology Rev. 9, 14-15 (2000) (*Vaccines, Coming of Age*). This strategy would avoid underimmunization due to missed doses and permit faster responses to epidemics. But conceivably the adjudvant might provoke a rare side effect—one the Georgia court might label "avoidable" because the vaccine could have been administered without the adjuvant.

- *Cell-based influenza vaccine.* Currently, many influenza vaccines—including most for seasonal

influenza—are produced in chicken eggs, a process that takes several months. *Vaccines* 266. Novel and much more rapid cell-based approaches to producing influenza vaccines are under development. See *Ibid.*; Nat'l Inst. of Allergy & Infectious Diseases, Dep't of Health & Human Servs., *The Jordan Report: Accelerated Development of Vaccines 2007*, App. A at 132 (May 2007). The ability to begin production closer to the flu season would improve the accuracy of predicting which strains will be dominant in a given year, and would allow manufacturers to respond to late-appearing strains. See Manon M.J. Cox, *Cell-Based Protein Vaccines for Influenza*, 7 Current Opinion in Molecular Therapeutics 24, 24-26 (2005). Faster production would also allow swifter response to pandemic flu outbreaks. See *id.* at 26; Homeland Sec. Council, *National Strategy for Pandemic Influenza: Implementation Plan* 105 n.16 (May 2006). But as with any new technique, cell-based approaches to producing vaccines could have side effects—and the Georgia court could label these side effects "avoidable" because the vaccines could instead have been produced using chicken eggs.

- *DNA vaccines.* Most vaccines work by introducing a harmless substance (such as a partial or inactivated virus or toxin) that teaches the body to recognize the molecular characteristics of a pathogen, so that the immune system will react swiftly in response to a true threat. See CDC, Dep't of Health & Human Servs., *How Vaccines Prevent Disease* (last modified Aug. 7, 2009) <http://www.cdc.gov/vaccines/vac-gen/howvpd.

htm>. DNA vaccines operate by introducing DNA sequences that prompt the body itself to make a small amount of the teaching substance. See *Vaccines, Coming of Age* 15-16. The technique promises new vaccines and more effective versions of existing vaccines. See *Jordan Report* App. A (listing DNA vaccines under development). But any side effects could be "avoidable" on the Georgia court's view if an injured party could point to the older version of the vaccine as an alternative.

3. Withdrawal of a manufacturer from the vaccine market for fear of design defect liability could have substantial public health consequences. As noted above, the Congress that passed the Act was concerned about just such instability and unpredictability in the vaccine market. Congress anticipated that the Act would give manufacturers "a better sense of their potential litigation obligations" and that, as a result, "a more stable childhood vaccine market [would] evolve," *1986 Report* 7. But as amici the American Academy of Pediatrics et al. stress (Br. 19-20), vaccines still are produced by very few manufacturers.

The Georgia court's decision could affect the existing balance. To be sure, predicting what a vaccine manufacturer might do in the future is inherently speculative. Manufacturers' potential liability for cases like this one and *Bruesewitz* lies principally in past events. The DTP vaccine that allegedly caused the *Bruesewitz* plaintiffs' daughter's injuries is no longer administered to children in the United States; similarly, the preservative thimerosal, which allegedly caused respondents' son's injuries, is no longer used in vaccines routinely administered to

infants and young children in the United States.[7] But the withdrawal in the future of even one of the handful of manufacturers producing vaccines could lead to a vaccine shortage. That shortage would not only risk disease for those left unvaccinated, but create conditions in which disease could run freely throughout the community. That is because vaccines are administered not only to immunize individuals, but also "to reduce transmission of infection and thereby to prevent disease even in non-vaccinated individuals, thus to protect communities." *Vaccines* 1573.[8]

III. *BRUESEWITZ* IS THE APPROPRIATE VEHICLE FOR RESOLUTION OF THE QUESTION PRESENTED

Respondents' voluntary dismissal in state court raises a substantial question concerning mootness that did not exist when this Court called for this Office's views. See Resp. Supp. Br. 1-2; Pet. Supp. Br. 3-5. Petitioners are correct that the Court has occasionally found a case to remain live notwithstanding post-petition developments that seemingly ended the controversy be-

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[7] The exceptions to this are certain influenza vaccines preserved with thimerosal, and certain other vaccines containing trace amounts of thimerosal. See FDA, Dep't of Health & Human Servs., *Thimerosal in Vaccines* tbl. 1 (last modified Nov. 6, 2009) <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm>.

[8] Congress and the Secretary have demonstrated a similar concern in responding to threats like the H1N1 influenza pandemic. See 42 U.S.C. 247d-6d (added by Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-146, Div. C, § 2, 119 Stat. 2818) (barring liability for designated vaccines and other countermeasures, except for cases of "willful misconduct"); 74 Fed. Reg. 30,294 (2009) (designating H1N1 vaccines—which, unlike the trivalent seasonal influenza vaccine, are not subject to the Vaccine Act—for such protection).

tween the parties. But none of the cases the parties cite from this Court's mootness jurisprudence squarely addresses the precise situation here. See *City News & Novelty, Inc.* v. *City of Waukesha*, 531 U.S. 278, 282-286 (2001); *City of Erie* v. *Pap's A.M.*, 529 U.S. 277, 288 (2000); *Deakins* v. *Monaghan*, 484 U.S. 193, 199-201 (1988). And no party suggests the threshold mootness question is independently certworthy.

Because *Bruesewitz* is a suitable alternative vehicle, the Court can address the important legal question here while avoiding the mootness issue. *Bruesewitz* appears jurisdictionally sound,[9] and the questions presented in that case and this one are materially identical. The claims in *Bruesewitz* (which involve administration of a particular DTP vaccine) are not representative of the claims in the OAP (which involve administration of MMR and thimerosal-containing vaccines), but that difference is legally immaterial. Organizations aligned with OAP claimants would likely present their views as

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[9] The *Bruesewitz* plaintiffs challenged the defendant manufacturer's removal of the case to federal court on diversity of citizenship grounds, asserting that all parties were Pennsylvania citizens. Applying the Third Circuit's multi-factor "center of corporate activities" test to decide the manufacturer's "principal place of business," the district court concluded that the manufacturer was a citizen of New Jersey (and Delaware, where it is incorporated), and thus diverse. *Bruesewitz* v. *Wyeth, Inc.*, No. 05-5994, Docket entry No. 13 (E.D. Pa. Mar. 27, 2006).

This Court's decision in *Hertz Corp.* v. *Friend*, No. 08-1107 (argued Nov. 10, 2009)—which concerns the test for deciding a corporation's "principal place of business" under 28 U.S.C. 1332(c)(1)—is unlikely to nullify the district court's jurisdiction in *Bruesewitz*. The manufacturer (whose executive offices are in New Jersey) would certainly be a citizen of New Jersey under the *Hertz* petitioner's proposed "headquarters" test, and likely would also be a citizen of that State under the *Hertz* respondent's proposed multi-factor test.

amici curiae in *Bruesewitz*—as they have already done at the petition stage, see National Vaccine Information Center et al. Amici Br. 2, *Bruesewitz*, *supra*. Likewise, manufacturers of vaccines at issue in the OAP would be able to present their views in *Bruesewitz*.

Accordingly, the Court should grant the petition in *Bruesewitz*. The Court could hold the petition in this case pending *Bruesewitz*, or else simply deny the petition to avoid the idiosyncratic mootness question, cf. *ASARCO Inc.* v. *Kadish*, 490 U.S. 605, 621 n.1 (1989).

CONCLUSION

The petition for a writ of certiorari should be held pending the disposition of *Bruesewitz* v. *Wyeth, Inc.*, petition for cert. pending, No. 09-152, or be denied. The petition for a writ of certiorari in *Bruesewitz* should be granted.

Respectfully submitted.

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JANUARY 2010